CENTER FOR MEDICAL CONSUMERS

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April 19, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: *Draft Guidance for Industry and FDA: "Consumer-Directed Broadcast Advertising of Restricted Devices* **Docket # 2004D-0042**

We are responding to the request for comments and suggestions regarding the above draft guidance for industry. The assumptions described in the Background regarding the accuracy, completeness and fairness of information communicated in these ads are not supportable. Consequently, the FDA should delay final action pending a complete review of the existing guidelines for the promotion of medical devices to consumers and health care professionals.

Our experience filing complaints with the FDA regarding General Electric's misleading promotion of digital mammography over two years ago has been instructive. We learned that the FDA allows manufacturers to make insupportable claims in their ads as long as the brand name of the equipment is not identified in the promotional materials. Now that more and more expensive, new technologies, such as ThinPrep and MRIs for breast screening, are sold directly to the public, the FDA must strengthen its guidance for industry—far beyond the proposals in this draft.

At a time when the entire U.S. health care system is under tremendous financial strain, continuing to permit inaccurate portrayal of new, expensive technologies is indefensible. We call on the FDA to provide effective oversight of all medical device ads whether or not the brand name is specified. The FDA must hold manufacturers accountable when they are found to be misleading the public. A misleading ad should be pulled immediately and the offending manufacturer should be required to run a corrective ad and with the same placements as the ad being corrected.

Medical device ads should also be required to feature risk information in the body of the advertisement. Since many of the new technologies, such as heart and whole-body scans, are being promoted to the public as screening tests, it is important for the public to have risks described in the body of the ads. The entrepreneurial radiologists promoting these tests should be required to identify the risks in their advertising, including radiation-induced cancers, unnecessary biopsies and the finding of cancers that would remained dormant and symptomless. By the way, whole-body and heart scans for screening are an "off label" use. Why does the FDA permit this type of advertising?

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Finally, the public would be well served if all consumer-directed broadcast and print ads had a brief statement about the inherent limitations of the FDA approval process in all print ads. The statement should caution the public that information about the safety and effectiveness of new devices is limited at the time of FDA approval. The statement for digital mammography, for example, could read: "The use of digital mammography for screening symptomless women has not been proven to be superior to standard mammography in terms of breast cancer mortality reduction."

Respectfully submitted,

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